4. 510(k) Summary according to 807.92

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Reverse Medical Corporation is providing the summary of Substantial Equivalence for the Reverse Medical Microcatheter.

4.1 Sponsor /Applicant Name and Address

Reverse Medical Corporation
13700 Alton Parkway
Suite 167
Irvine, CA 92618

DEC 0 7 2012

4.2 Sponsor Contact Information

Linda D'Abate, Vice President RA/CA/QA
Phone: 949-215-0660 x202 Mobile 714-235-6608
Fax: 949-215-0661
Email: ldabate@reversemed.com

4.3 Date of Preparation of 510(k) Summary

August 31, 2012

4.4 Device Trade or Proprietary Name

Reverse Medical Microcatheter

4.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY) and Catheter, Infusion (Product Code KRA)

4.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Devices	Name of Manufacturer (Town, State)	510(k) Number
Headway™ Microcatheter	MicroVention, Inc. Tustin, CA	K083343
ev3 Rebar-18	Covidien Mansfield, MA	K001966

510(k) Summary according to 807.92 (continued)

4.7 Device Description

The Reverse Medical Microcatheter is a single lumen, flexible, variable stiffness composite catheter. The catheter shaft has a hydrophilic coating to reduce friction during use. The Reverse Medical Microcatheter dimensions are included on the individual device labels. The Reverse Medical Microcatheter inner lumen can accommodate guidewires up to 0.018 inches in diameter to access distal tortuous vasculature. Dual radiopaque markers at the distal portion of the catheter facilitate fluoroscopic visualization.

The Reverse Medical Microcatheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

4.8 Intended Use

The Reverse Medical Microcatheter is intended for use in neuro, peripheral, and coronary vasculature. The Reverse Medical Microcatheter coaxially tracks over a steerable guidewire in order to access distal tortuous vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

4.9 Comparison to Predicate Devices

	MicroVention Headway™ Microcatheter	**ev3 Rebar-18**	**Reverse Medical Microcatheter**
510(k) Number	K083343	K001966	TBD
Classification	Class II, DQY	Class II, KRA	Class II, DQY
Indication	Intended for use in neuro, peripheral, and coronary vasculature for the infusion of diagnostic agents, such as contrast media and therapeutic agents such as occlusion coils	Intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy	Intended for use in neuro, peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils
Shaft Materials	Coaxial lumen braided shaft variable stiffness catheter with radiopaque marker on distal end.	Semi-rigid proximal shaft that transitions into the flexible distal shaft with single or dual radiopaque markers at the distal end.	Single lumen, wire reinforced shaft, variable stiffness catheter with dual radiopaque markers on distal end.
Proximal End Configuration	Luer Hub	Luer Hub	Luer Hub
Radiographic markers/radiopacity	Dual radiopaque marker at distal tip	Single or dual radiopaque markers at distal end of shaft.	Dual radiopaque marker at distal tip
Packaging	Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton.	Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton.	Polyethylene hoop and PET/PE/Tyvek pouch inside SBS carton.
Sterilization	EtO	EtO	EtO

510(k) Summary according to 807.92 (continued)

4.10 Summary of Non-Clinical Data

4.10.1 Biocompatibility and Sterilization

The Reverse Medical Microcatheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hours). Results of the testing demonstrate that the blood-contacting materials are biocompatible.

Blood-contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1 guidelines "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The Reverse Medical Microcatheter successfully passed all of the following biocompatibility tests:

Test	Method
Cytotoxicity	L929 MEM Elution Test
Sensitization	Kligman Maximization
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test
Hemocompatibility	Complement Activation
	Hemolysis
	Inactivated Partial Thromboplastin Time Test
	In vivo thrombogenicity
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test
EtO Residuals	Ethylene oxide and Ethylene chlorohydrins residuals

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

4.10.2 Design Verification (Bench-Top Testing)

The physical, mechanical, and performance testing of the Reverse Medical Microcatheter demonstrate that the product is substantially equivalent to the currently marketed predicate devices. Design verification testing was conducted to evaluate the physical and mechanical properties of the Reverse Medical Microcatheter. All studies were conducted in accordance with Reverse Medical Design Control procedures. All testing was performed on units that were sterilized and met all inspection criteria. Tests on the Reverse Medical Microcatheter included:

Verification and Test Summary

***In vitro* Tests**	**Result**
Dimensional and Visual Inspection	Met established criteria
Coating Lubricity	Met established criteria
Tip Buckling	Met established criteria
Flexibility/Shaft Stiffness Test	Met established criteria
Flow Rate Test – 100 psi and 300 psi	Met established criteria
Priming Volume Test	Met established criteria
Kink Resistance Test	Met established criteria
Guidewire Compatibility	Met established criteria
Guide Catheter Compatibility	Met established criteria
Catheter Leak Test (Air leakage distal end plugged)	Met established criteria
Catheter Leak Test (Liquid leakage)	Met established criteria
Dynamic Pressure Test	Met established criteria
Static Burst Test	Met established criteria
Torque Strength (Turns to Failure)	Met established criteria
Tensile Strength Test	Met established criteria
Corrosion Resistance	Met established criteria
USP Particulate Test	Met established criteria
Navigation Capabilities, Accessibility/Pushability Capabilities, Therapeutic Agents Deliverability (Coils and Stents)	Met established criteria
***In vivo* Tests**	**Result**
System Deliverability, Compatibility, and Visibility	Met established criteria
Biocompatibility Testing	Met established criteria

The physical, mechanical, and performance testing of the Reverse Medical Microcatheter demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices.

4.11 Substantial Equivalence

The performance of the Reverse Medical Microcatheter in this submission demonstrates that the product is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specifications, performance, biocompatibility testing, and sterilization validation.

The Reverse Medical Microcatheter is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the predicate devices. Differences between the devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 7 2012

Reverse Medical Corporation
Mr. Jeffrey Valko
President & CEO
13700 Alton Parkway Suite 167
Irvine, CA 92618 US

Re: K122684
Trade/Device Name: Reverse medical microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: November 8, 2012
Received: November 9, 2012

Dear Mr. Valko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

3. Indications for Use

510(k) Number (if known): K122684

Device Name: Reverse Medical Microcatheter

Indications for Use:

The Reverse Medical Microcatheter is intended for use in neuro, peripheral and coronary vasculature for the infusion of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over the Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122684